



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,412	12/06/2000	Howard Bernstein	ACU 105 DIV(2)	9414

23579 7590 02/05/2002

PATREA L. PABST
HOLLAND & KNIGHT LLP
SUITE 2000, ONE ATLANTIC CENTER
1201 WEST PEACHTREE STREET, N.E.
ATLANTA, GA 30309-3400

EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 02/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/731412

Applicant(s)

BERNSTEIN

Examiner

W EBMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 12/6/00
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 21-34 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 21-34 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 20-31, 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Hanes et al.

Hanes et al teach delivery of microparticles to the pulmonary system comprising polylactic acid and dipalmitoyl phosphatidylcholine (DPPC). The latter be incorporated in the material forming the particle (abstract). Dissolution of DPPC in the polymer solution is specified (column 13 lines 55-57). A ratio of 3 mg DPPC to 50 mg (lactic coglycolic acid) is specified (column 13 lines 44-45). Palmitic acid is disclosed as equivalent to DPPC (column 5 lines 39-46). Testosterone, which is insoluble in water, is specified (column 10 line 47). Polysaccharides and proteins are further disclosed as polymers (column 6 line 24) as is polyacrylic acid (line 24), well-known as an adhesive polymer.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 20-24, 27-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Gombotz et al.

Gombotz et al teach injection or transmucosal delivery of microparticles comprising polylactic acid or a biadhesive polymer (abstract).

Cellulose is disclosed (column 5 line 21), 0.1%-10% and active is specified (column 9 lines 18-19). 4:1 lipid to active is disclosed (column 10 line 7). Phospholipids are disclosed (column 10 line 8).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-24, 27-30, 31, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanke.

Hanke et al teaches application of a suppository comprising a thermoplastic polymer having a lubricant dispersed throughout (abstract, claim 1). Actives are specified (column 13 line 15 et seq.), Hydroxypropyl cellulose is specified (column 3 line 45). Fats and mineral oil are disclosed (column 3 lines 55-56). 35 grams oil in 195 grams of vehicle is disclosed (column 8 lines 18-21).

As to the claimed amount of hydrophobic compound, the above anticipatory references teach an amount which reads on the broad ranges claimed by applicants to achieve applicants' intended effect.

No claims allowed.

The parent application is unavailable at this writing. Applicants' IDS will be considered in the next action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edwards J. Webman whose telephone number is 308-4432. The examiner can normally be reached on Monday to Friday from 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Webman/LR

January 17, 2002


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500